

JUN 24 2003

Special 510(k): Device Modification

**ZMR® Hip System-XL**  
**Summary of Safety and Effectiveness**

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**Submitter:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Karen Cain  
Manager, Regulatory Affairs  
Telephone: (574) 372-4219  
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**Date:** May 16, 2003

**Trade Name:** ZMR® Hip System-XL

**Common Name:** Total hip prosthesis

**Classification Name**  
**and Reference:** Hip joint metal/polymer semiconstrained  
uncemented prosthesis, no 21 CFR reference

**Predicate Devices:** Hip joint metal/polymer/metal semiconstrained  
porous coated uncemented prosthesis, 21 CFR  
888.3358

**Predicate Devices:** ZMR® Hip System-Revision Taper, manufactured  
by Zimmer, Inc., K992667, cleared October 27,  
1999

**Predicate Devices:** ZMR® Hip System-Porous Revision, manufactured  
by Zimmer, Inc., K994286, cleared March 10, 2000

**Device Description:** Like its predicates, the ZMR® Hip System-XL  
prosthesis is a modular femoral stem manufactured  
from *Titanium*® Ti-6Al-4V Alloy and intended for  
cementless use in revision hip arthroplasty. This  
device has two modular junctions: a head/neck  
junction and a midstem junction. Three  
components are intraoperatively assembled to  
construct the device: a proximal "body," a distal  
stem, and a compression nut.

**Intended Use:**

The ZMR<sup>®</sup> Hip Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.

**Comparison to Predicate Device:**

The modifications to the ZMR<sup>®</sup> Hip System change neither the intended use nor the fundamental scientific technology of the device. The ZMR XL components are manufactured, packaged and sterilized using the same processes and materials.

**Performance Data:**

Non-clinical performance testing demonstrated that the device is equivalent to the predicate.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Zimmer, Inc.  
% Mr. Daniel Williman  
Associate Project Manager, Regulatory Affairs  
P.O. Box 708  
Warsaw, Indiana 46581-0708

FEB - 3 2012

Re: K031572

Trade/Device Name: ZMR™ Hip System-XL

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: II

Product Code: LPH, LZO, LWJ

Dated: May 16, 2003

Received: June 3, 2003

Dear Mr. Williman:

This letter corrects our substantially equivalent letter of June 24, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

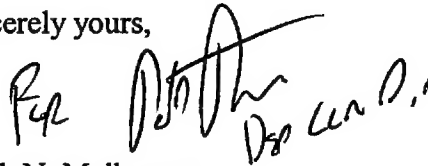
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic, and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K031572

Device Name:

ZMR<sup>®</sup> Hip System – XL

Indications for Use:

The ZMR Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

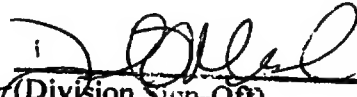
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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